

# Exhibit A

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

Civ. No. 19-2875 (RBK/JS)

*All Actions*

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO AUROBINDO PHARMA LIMITED, AUROBINDO USA, INC., AND  
AUROLIFE, LLC PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Jessica M. Heinz, Esq.  
Cipriani & Werner  
450 Sentry Parkway, Suite 200  
Blue Bell, PA 19422

*Counsel for Defendants Aurobindo Pharma Limited, Aurobindo USA, Inc. and Aurolife  
Pharma, LLC*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on December 2, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Aurobindo Pharma Limited, Aurobindo USA, Inc. and Aurolife Pharma, LLC, and Defendants' liaison counsel, via email.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater  
Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

## **EXHIBIT A**

All topics reference information and documents known to, and/or in the possession, custody, or control, of Aurobindo, in the ordinary course of its business.

All references to Aurobindo refer to all entities involved in the manufacture of valsartan API and/or finished dose sold by Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc. and/or Aurolife Pharma, LLC in the United States.

All references to the “API,” or Aurobindo’s API are defined to include the valsartan API manufactured, sold, or distributed by Aurobindo, which was manufactured in the facilities that manufactured valsartan API sold in the United States.

All references to “finished dose” or Aurobindo’s finished dose are defined to include all valsartan finished dose manufactured by Aurobindo, which was manufactured in the facilities that manufactured valsartan finished dose sold in the United States.

In accordance with the Court’s Macro Discovery Order (ECF Doc No. 303), the terms “communications with any regulatory authority,” “disclosures to regulatory authorities,” and “filings with regulatory authorities” are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of Aurobindo API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)

- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

### **Nitrosamine Contamination**

1. The cause of the contamination of Aurobindo's valsartan API with nitrosamines, including, but not limited to, NDMA and NDEA.
2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the Aurobindo API.
3. Any assessment or root cause analysis conducted by Lantech Pharmaceuticals with regards to NDMA and NDEA contamination in recycled or recovered solvents.

### **Testing**

4. The testing performed by Aurobindo or its agents, to evaluate the purity and contents of Aurobindo's API.
5. The testing performed by any entity or person other than Aurobindo or its agents but known to Aurobindo, to evaluate the purity and contents of Aurobindo's valsartan API.
6. The testing performed by Aurobindo or its agents, to evaluate the purity and contents of Aurobindo's finished dose.
7. The testing performed by Aurobindo or its agents to evaluate the purity and contents of recovered or recycled solvents provided by Lantech Pharmaceuticals.
8. The testing performed by any entity or person other than Aurobindo or its agents but known to Aurobindo, to evaluate the purity and contents of Aurobindo's finished dose.
9. The chromatogram and mass spectrometry results for all testing by Aurobindo or its agents of Aurobindo's valsartan API.
10. The chromatogram and mass spectrometry results for all testing by any entity or person other than Aurobindo or its agents but known to Aurobindo, of Aurobindo's valsartan API.
11. The chromatogram and mass spectrometry or other results for all testing by Aurobindo or its agents of Aurobindo's finished dose.
12. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Aurobindo or its agents but known to Aurobindo, of Aurobindo's finished dose.

13. Aurobindo's evaluation of the potential risks to the purity or contents of Aurobindo's API posed or caused by solvents used during the manufacturing process.
14. The chromatogram and mass spectrometry results for all testing by Aurobindo or its agents of the solvents utilized in the manufacture of Aurobindo's valsartan API.
15. The chromatogram and mass spectrometry results for all testing by any entity or person other than Aurobindo or its agents but known to Aurobindo, of the solvents utilized in the manufacture of Aurobindo's API.
16. The extent of the actual and potential nitrosamine contamination of Aurobindo's valsartan API and valsartan finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

**Quality Assurance and Quality Control Activities**

17. Aurobindo's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Aurobindo's valsartan API. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
18. Aurobindo's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Aurobindo's valsartan finished dose. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
19. Aurobindo's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Aurobindo's valsartan API. (The parties to meet and confer to identify the relevant cGMP's.)
20. Aurobindo's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Aurobindo's valsartan finished dose. (The parties to meet and confer to identify the relevant cGMP's.)
21. Aurobindo's SOPs/policies/procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with procurement of recovered or recycled solvents, and selection of vendors to provide such services. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)

**Process Development**

22. The development of each Drug Master File, including any risk assessments conducted on starting materials, or solvents, for Aurobindo's valsartan API.
23. The use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Aurobindo's valsartan API, including: (1) the reasons for each, and any modifications, (2) the testing and evaluation in connection with each, including any modification, and (3) the relationship between each, including any modifications, and the nitrosamine contamination of Aurobindo's valsartan API.
24. Any evaluation conducted by or on behalf of Aurobindo with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, and in particular potential nitrosamine impurities, in the manufacturing process for Aurobindo's valsartan API.
25. Aurobindo's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for Aurobindo's valsartan API.
26. Aurobindo's evaluation and knowledge of the risks of using recovered or recycled solvents in the manufacture of Aurobindo's API and finished dose.
27. Aurobindo's evaluation and knowledge of the health risks of exposure to nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Aurobindo's valsartan API.
28. Aurobindo's evaluation and knowledge of the health risks of exposure to nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Aurobindo's valsartan finished dose.

**Communications with Regulatory Agencies**

29. The communications with any regulatory authority, including but not limited to the FDA, with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Aurobindo's valsartan API.
30. Aurobindo's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Aurobindo's valsartan API with nitrosamines including NDMA and NDEA.
31. Aurobindo's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Aurobindo's valsartan finished dose with nitrosamines including NDMA and NDEA.
32. Aurobindo's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for Aurobindo's Valsartan API Drug Master Filings.



**Aurobindo's Communications with Finished Dose Customers and Downstream Customers**

33. Aurobindo's oral and written communications with its valsartan API Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Aurobindo API.
34. Aurobindo's oral and written communications with its valsartan finished dose Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Aurobindo finished dose.
35. Aurobindo's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Aurobindo's valsartan API.
36. Aurobindo's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Aurobindo's valsartan finished dose.
37. Aurobindo's product recall for valsartan API, including who Aurobindo communicated with, how, about what, and the retention of recalled or sequestered Aurobindo valsartan API, including as a component of finished dose.
38. Aurobindo's product recall for valsartan finished dose, including who Aurobindo communicated with, how, about what, and the retention of recalled or sequestered Aurobindo valsartan finished dose.
39. All credits, indemnification, refunds, and/or penalties paid or provided by or to Aurobindo (i.e. to/from customers, regulatory agencies) in connection with the nitrosamine contamination of Aurobindo's valsartan API and finished dose.

**Compliance with cGMPs**

40. Aurobindo's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of Aurobindo's API and finished dose. (The parties to meet and confer to identify the relevant cGMP's.)
41. The policies, practices, procedures and trainings for monitoring compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in the manufacture of Aurobindo's valsartan API and valsartan finished dose. (The parties to meet and confer to identify the relevant cGMP's.)
42. The policies, practices, procedures and trainings intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic

impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, for monitoring material providers (such as Lantech Pharmaceuticals) and their compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents,. (The parties to meet and confer to identify the relevant cGMP's.)

**Product Tracing**

43. Tracing of batches and lots of Aurobindo's valsartan API sold downstream and ultimately intended for use by consumers in the United States. (the parties to meet and confer to identify relevant documents).
44. Tracing of batches and lots of Aurobindo's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States. (the parties to meet and confer to identify relevant documents).
45. The pricing of Aurobindo's valsartan API that was ultimately sold in the United States (the parties to meet and confer to identify relevant documents).
46. The pricing of Aurobindo's valsartan finished dose that was ultimately sold in the United States (the parties to meet and confer to identify relevant documents).
47. The gross and net profits to Aurobindo from the sale of Aurobindo's valsartan API in the United States (the parties to meet and confer to identify relevant documents).
48. The gross and net profits to Aurobindo from the sale of Aurobindo's valsartan finished dose in the United States (the parties to meet and confer to identify relevant documents).
49. The quantity/units of Aurobindo's valsartan finished dose sold in the United States (the parties to meet and confer to identify relevant documents).
50. Aurobindo's valsartan API sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).
51. Aurobindo's valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).

## Exhibit B

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

Civ. No. 19-2875 (RBK/JS)

*All Actions*

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO HETERO LABS LIMITED, HETERO DRUGS, LIMITED,  
PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Eric Abraham, Esq.  
Hill Wallack LLP  
21 Roszel Road  
Princeton, NJ 08540

*Counsel for Defendants Hetero Labs Limited and Hetero Drugs, Limited*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 2nd day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater

103 Eisenhower Parkway, Suite 207

Roseland, New Jersey 07068

Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on December 2, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Hetero Labs Limited, Hetero Drugs, Limited, Hetero USA Inc., and Camber Pharmaceuticals, Inc., and Defendants' liaison counsel, via email.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**EXHIBIT A**

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues and the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

All topics reference information and documents known to, and/or in the possession, custody, or control, of HLL, in the ordinary course of its business.

All references to HLL refer to all entities involved in the manufacture of HLL's valsartan API and/or finished dose, including Hetero Labs, Limited, and Hetero Drugs, Limited.

All references to the "API," or HLL's API are defined to include the valsartan API manufactured, sold, or distributed by HLL, which was manufactured in the facilities that manufactured valsartan API sold in the United States.

All references to "finished dose" or HLL's finished dose are defined to include the valsartan finished dose manufactured, sold, or distributed by HLL, which was manufactured in the facilities that manufactured valsartan finished dose sold in the United States.

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of HLL's valsartan API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)

- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

### **Nitrosamine Contamination**

1. The cause of the contamination of HLL's valsartan API with nitrosamines, including, but not limited to, NDMA and NDEA.
2. The cause of the contamination of HLL's valsartan finished dose with nitrosamines, including, but not limited to, NDMA and NDEA.
3. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the HLL API.
4. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the HLL valsartan finished dose.
5. The genotoxic analysis performed by HLL on 4-Bromomethyl-2'cyano biphenyl in response to the FDA's inquiry as part of the Drug Master File submission.

### **Testing**

6. The testing performed by HLL or its agents, to evaluate the purity and contents of HLL's API.
7. The testing performed by any entity or person other than HLL or its agents but known to HLL, to evaluate the purity and contents of HLL's valsartan API.
8. The testing performed by HLL or its agents, to evaluate the purity and contents of HLL's finished dose.
9. The testing performed by any entity or person other than HLL or its agents but known to HLL, to evaluate the purity and contents of HLL's finished dose.
10. The chromatogram and mass spectrometry results for all testing by HLL or its agents of HLL's valsartan API.
11. The chromatogram and mass spectrometry results for all testing by any entity or person other than HLL or its agents but known to HLL, of HLL's valsartan API.



12. The chromatogram and mass spectrometry or other results for all testing by HLL or its agents of HLL's finished dose.
13. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than HLL or its agents but known to HLL, of HLL's finished dose.
14. HLL's evaluation of the potential risks to the purity or contents of HLL's API posed or caused by solvents used during the manufacturing process.
15. The chromatogram and mass spectrometry results for all testing by HLL or its agents of the solvents utilized in the manufacture of HLL's valsartan API.
16. The chromatogram and mass spectrometry results for all testing by HLL or its agents of the solvents utilized in the manufacture of HLL's valsartan finished dose.
17. The chromatogram and mass spectrometry results for all testing by any entity or person other than HLL or its agents but known to HLL, of the solvents utilized in the manufacture of HLL's API.
18. The chromatogram and mass spectrometry results for all testing by any entity or person other than HLL or its agents but known to HLL, of the solvents utilized in the manufacture of HLL's valsartan finished dose.
19. The extent of the actual and potential nitrosamine contamination of HLL's valsartan API and valsartan finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

**Quality Assurance and Quality Control Activities**

20. HLL's SOPs/policies/procedures intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of HLL's valsartan API.
21. HLL's SOPs/policies/procedures intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of HLL's valsartan finished dose.
22. HLL's application of cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of HLL's valsartan API.
23. HLL's application of cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of HLL's valsartan finished dose.

24. HLL's SOPs/policies/procedures for determining when it is appropriate to conduct a genotoxic analysis of the process associated with API manufacturing.
25. HLL's SOPs/policies/procedures for determining when it is appropriate to conduct a genotoxic analysis of the process associated with finished dose manufacturing.

#### **Process Development**

26. The development of each Drug Master File for HLL valsartan API sold in the United States, including any risk assessments conducted on starting materials, or solvents.
27. The use of solvents, and the Tetrazole ring formation step, in the manufacturing process for HLL's valsartan API, including: (1) the reasons for each, and any modifications, (2) the testing and evaluation in connection with each, including any modification, and (3) the relationship between each, including any modifications, and the nitrosamine contamination of HLL's valsartan API.
28. Any evaluation conducted by or on behalf of HLL with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for HLL's valsartan API.
29. HLL's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for HLL's valsartan API.
30. HLL's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of HLL's valsartan API.
31. HLL's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of HLL's valsartan finished dose.

#### **Communications with Regulatory Agencies**

32. The communications with any regulatory authority, including but not limited to the FDA, with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for HLL's valsartan API.
33. HLL's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of HLL's valsartan API with nitrosamines including NDMA and NDEA.
34. HLL's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for HLL's Valsartan API Drug Master Filings for the valsartan API sold in the United States.

#### **HLL's Communications with Finished Dose Customers and Downstream Customers**

35. HLL's oral and written communications with its valsartan API Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the HLL API.
36. HLL's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of HLL's valsartan API.
37. HLL's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of HLL's valsartan finished dose.
38. HLL's product recall for valsartan API, including who HLL communicated with, how, about what, and the retention of recalled or sequestered HLL valsartan API, including as a component of finished dose.
39. HLL's product recall for valsartan finished dose, including who HLL communicated with, how, about what, and the retention of recalled or sequestered HLL valsartan finished dose.
40. All credits, indemnification, refunds, and/or penalties paid or provided by or to HLL in connection with the nitrosamine contamination of HLL's valsartan API and finished dose.

#### **Compliance with cGMPs**

41. HLL's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of HLL's valsartan API.
42. HLL's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of HLL's valsartan finished dose.
43. The policies, practices, procedures and trainings for monitoring compliance with cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in the manufacture, quality assurance, quality control, and sale of HLL's valsartan API.
44. The policies, practices, procedures and trainings for monitoring compliance with cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in the manufacture, quality assurance, quality control, and sale of HLL's valsartan finished dose.

#### **Product Tracing**

45. Tracing of batches and lots of HLL's valsartan API sold downstream and ultimately intended for use by consumers in the United States.
46. Tracing of batches and lots of HLL's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.
47. The pricing of HLL's valsartan API that was ultimately sold in the United States.
48. The pricing of HLL's valsartan finished dose that was ultimately sold in the United States.
49. The gross and net profits to HLL from the sale of HLL's valsartan API in the United States.
50. The gross and net profits to HLL from the sale of HLL's valsartan finished dose in the United States.
51. The quantity/units of HLL's valsartan finished dose sold in the United States.
52. HLL's valsartan API sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).
53. HLL's valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).

## Exhibit C

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

Civ. No. 19-2875 (RBK/JS)

*All Actions*

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO MYLAN LABORATORIES, LTD., MYLAN N.V., AND  
MYLAN PHARMACEUTICALS, INC. PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Clem Trischler, Esq.  
Pietragallo Gordon Alfano Bosick & Raspanti LLP  
One Oxford Centre  
38th Floor  
Pittsburgh, PA 15219

*Counsel for Defendants Mylan Laboratories, Ltd., Mylan N.V., and Mylan  
Pharmaceuticals, Inc.*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date and time to be determined, at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater

103 Eisenhower Parkway, Suite 207

Roseland, New Jersey 07068

Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on December 2, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Mylan Laboratories, Ltd., Mylan N.V., and Mylan Pharmaceuticals, Inc., and Defendants' liaison counsel, via email.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***



**EXHIBIT A**

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; and the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

All topics reference information and documents known to, and/or in the possession, custody, or control of Mylan, in the ordinary course of its business.

All references to Mylan refer to all entities under the control of Mylan Laboratories, Ltd., Mylan N.V., and/or Mylan Pharmaceuticals, Inc. involved in the manufacture of valsartan API and/or finished dose sold in the United States.

All references to the "API," Mylan's API, or Mylan's valsartan API are defined to include the valsartan API manufactured, sold, or distributed by Mylan, which was manufactured in the facilities that manufactured valsartan API sold in the United States.

All references to "finished dose," Mylan's finished dose, or Mylan's valsartan finished dose are defined to include the valsartan finished dose manufactured, sold, or distributed by Mylan, which was manufactured in the facilities that manufactured valsartan finished dose sold in the United States.

In accordance with the Court's Macro Discovery Order (Dkt. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined as testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of Mylan's valsartan API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)

- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

### **Testing**

1. The cause of the contamination of Mylan's valsartan API with nitrosamines, including, but not limited to, NDMA and NDEA.
2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the Mylan API.
3. Any assessment or root cause analysis conducted by Lantech Pharmaceuticals with regard to NDMA and NDEA contamination in recycled or recovered solvents.
4. The testing performed by Mylan or its agents, to evaluate the purity and contents of Mylan's API, (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.
5. The testing performed by any entity or person other than Mylan or its agents but known to Mylan, to evaluate the purity and contents of Mylan's valsartan API, (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.
6. The testing performed by Mylan or its agents, to evaluate the purity and contents of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
7. The testing performed by Mylan or its agents to evaluate the purity and contents of recovered or recycled solvents provided by Lantech Pharmaceuticals.
8. The testing performed by any entity or person other than Mylan or its agents but known to Mylan, to evaluate the purity and contents of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.

9. The chromatogram and mass spectrometry results for all testing by Mylan or its agents of Mylan's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.
10. The chromatogram and mass spectrometry results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of Mylan's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.
11. The chromatogram and mass spectrometry or other results for all testing by Mylan or its agents of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
12. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
13. Mylan's evaluation of the potential risks to the purity or contents of Mylan's API posed or caused by solvents used during the manufacturing process (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.
14. Mylan's evaluation of the potential risks to the purity or contents of Mylan's finished dose posed or caused by solvents used during the manufacturing process (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
15. The chromatogram and mass spectrometry results for all testing by Mylan or its agents of the solvents utilized in the manufacture of Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.
16. The chromatogram and mass spectrometry results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of the solvents utilized in the manufacture of Mylan's API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.
17. The chromatogram and mass spectrometry results for all testing by Mylan or its agents of the solvents utilized in the manufacture of Mylan's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
18. The chromatogram and mass spectrometry results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of the solvents utilized in the manufacture of Mylan's finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.

19. The extent of the actual and potential nitrosamine contamination of Mylan's valsartan API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

**Quality Assurance and Quality Control Activities**

20. Mylan's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
21. Mylan's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Mylan's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
22. Mylan's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant cGMPs.)
23. Mylan's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Mylan's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMPs.)
24. Mylan's SOPs/policies/procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, for procurement of recovered or recycled solvents, and selection of vendors to provide such services.

**Process Development**

25. The development of each Drug Master File for Mylan's valsartan API sold in the United States, including any risk assessments conducted on starting materials, or solvents.
26. The use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Mylan's valsartan API, including: (1) the reasons for each, and any modifications, (2)

the testing and evaluation in connection with each, including any modification, and (3) the relationship between each, including any modifications, and the nitrosamine contamination of Mylan's valsartan API, (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.

27. Any evaluation conducted by or on behalf of Mylan with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.
28. Mylan's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for Mylan's valsartan API.
29. Mylan's evaluation and knowledge of the risk of using recovered or recycled solvents in the Tetrazole ring formation step, in the manufacturing process for Mylan's valsartan API.
30. Mylan's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Mylan's valsartan API.
31. Mylan's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Mylan's valsartan finished dose.

#### **Communications with Regulatory Agencies**

32. The communications with any regulatory authority, including but not limited to the FDA, with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Mylan's valsartan API.
33. Mylan's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Mylan's valsartan API with nitrosamines including NDMA and NDEA.
34. Mylan's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Mylan's valsartan finished dose with nitrosamines including NDMA and NDEA.
35. Mylan's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for Mylan's Valsartan API Drug Master Filings.

#### **Mylan's Communications with Finished Dose Customers and Downstream Customers**

36. Mylan's oral and written communications with its valsartan API Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Mylan API.

37. Mylan's oral and written communications with its valsartan finished dose Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Mylan's finished dose.
38. Mylan's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Mylan's valsartan API.
39. Mylan's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Mylan's valsartan finished dose.
40. Mylan's product recall for valsartan API, including who Mylan communicated with, how, about what, and the retention of recalled or sequestered Mylan valsartan API, including as a component of finished dose.
41. Mylan's product recall for valsartan API, including who Mylan communicated with, how, about what, and the retention of recalled or sequestered Mylan valsartan finished dose.
42. All credits, indemnification, refunds, and/or penalties paid or provided by or to Mylan in connection with the nitrosamine contamination of Mylan's valsartan API and finished dose.

#### **Compliance with cGMPs**

43. Mylan's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of Mylan's API and finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API or finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMPs.)
44. The policies, practices, procedures and trainings for monitoring compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API or finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMPs.)
45. The policies, practices, procedures and trainings for monitoring material providers (such as Lantech Pharmaceuticals) and their compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents. (The parties to meet and confer to identify the relevant cGMPs.)

#### **Product Tracing**

46. Tracing of batches and lots of Mylan's valsartan API sold downstream and ultimately intended for use by consumers in the United States. (The parties to meet and confer regarding the scope of this area of examination.)
47. Tracing of batches and lots of Mylan's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States. (The parties to meet and confer to identify the relevant documents.)
48. The pricing of Mylan's valsartan API that was ultimately sold in the United States. (The parties to meet and confer to identify the relevant documents.)
49. The pricing of Mylan's valsartan finished dose that was ultimately sold in the United States. (The parties to meet and confer to identify the relevant documents.)
50. The gross and net profits to Mylan from the sale of Mylan's valsartan API in the United States. (The parties to meet and confer to identify the relevant documents.)
51. The gross and net profits to Mylan from the sale of Mylan's valsartan finished dose in the United States. (The parties to meet and confer to identify the relevant documents.)
52. The quantity/units of Mylan's valsartan finished dose sold in the United States. (The parties to meet and confer to identify the relevant documents.)
53. Mylan's valsartan API sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).
54. Mylan's valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).

## Exhibit D



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

Civ. No. 19-2875 (RBK/JS)

*All Actions*

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL  
INDUSTRIES LTD., ACTAVIS, LLC, ARROW PHARM MALTA LTD., AND ACTAVIS  
PHARMA, INC. PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Lori Cohen, Esq.  
Greenberg Traurig, LLP  
Terminus 200 Building, 25<sup>th</sup> Floor  
3333 Piedmont Road NE  
Atlanta, Georgia 30305

*Counsel for Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical  
Industries Ltd., Actavis, LLC, Arrow Pharm Malta Ltd., and Actavis Pharma, Inc.*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 2nd day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater

103 Eisenhower Parkway, Suite 207

Roseland, New Jersey 07068

Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on December 2, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis, LLC, Arrow Pharm Malta Ltd., and Actavis Pharma, Inc., and Defendants' liaison counsel, via email.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**EXHIBIT A**

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues and the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

All topics reference information and documents known to, and/or in the possession, custody, or control, of Teva, in the ordinary course of its business.

All references to Teva include Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, Arrow Pharm Malta Ltd., and Actavis Pharma, Inc.

All references to ZHP's valsartan API, or ZHP's API are defined to include the valsartan API manufactured, sold, or distributed by ZHP, which was manufactured in the ZHP facilities that manufactured valsartan API sold in the United States.

All references to Mylan's valsartan API, or Mylan's API are defined to include the valsartan API manufactured, sold, or distributed by Mylan, which was manufactured in the Mylan facilities that manufactured valsartan finished dose sold in the United States.

All references include all legacy entities (such as Actavis or Arrow entities in Malta) that purchased valsartan API and sold valsartan finished dose intended for use in the United States.

All references to the finished dose or Teva's finished dose are defined to include the valsartan finished dose manufactured, sold, or distributed by Teva, which was manufactured in the facilities that manufactured valsartan finished dose sold in the United States.

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of Teva's valsartan finished dose (including testing of ZHP and Mylan valsartan API utilized to manufacture Teva's valsartan finished dose), and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)

- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

**Testing of Valsartan API and Finished Dose**

1. The cause of the contamination of ZHP's valsartan API with nitrosamines including NDMA.
2. The cause of the contamination of Mylan's valsartan API with nitrosamines including NDMA.
3. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the ZHP API.
4. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the Mylan API.
5. The testing performed by Teva or its agents, to evaluate the purity and contents of ZHP's API.
6. The testing performed by Teva or its agents, to evaluate the purity and contents of Mylan's API.
7. The testing performed by Teva or its agents, to evaluate the purity and contents of Teva's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Teva's finished dose for sale in the United States.
8. The testing performed by any entity or person other than Teva or its agents but known to Teva, to evaluate the purity and contents of ZHP's valsartan API.
9. The testing performed by any entity or person other than Teva or its agents but known to Teva, to evaluate the purity and contents of Mylan's valsartan API.
10. The testing performed by any entity or person other than Teva or its agents but known to Teva, to evaluate the purity and contents of Teva's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Teva's finished dose for sale in the United States.
11. The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of ZHP's valsartan API.
12. The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of Mylan's valsartan API.
13. The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of Teva's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Teva's finished dose for sale in the United States.
14. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of ZHP's valsartan API.
15. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of Mylan's valsartan API.
16. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of Teva's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Teva's finished dose for sale in the United States.
17. Teva's evaluation of the potential risks to the purity or contents of ZHP's API posed or caused by solvents used during the ZHP API manufacturing process.
18. Teva's evaluation of the potential risks to the purity or contents of Mylan's API posed or caused by solvents used during the Mylan API manufacturing process.
19. Teva's evaluation of the potential risks to the purity or contents of Teva's finished dose posed or caused by solvents used during the Teva finished dose manufacturing process

- (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States. .
20. The chromatogram and mass spectrometry or other results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's valsartan API.
  21. The chromatogram and mass spectrometry or other results for all testing by Mylan or its agents of the solvents utilized in the manufacture of Mylan's valsartan API.
  22. The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of the solvents utilized in the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States.
  23. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to Teva, of the solvents utilized in the manufacture of ZHP's API.
  24. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Mylan or its agents but known to Teva, of the solvents utilized in the manufacture of Mylan's API.
  25. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of the solvents utilized in the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States.
  26. The chromatogram and mass spectrometry or other results for all testing by Teva or its agents of the production equipment utilized in the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States.
  27. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Teva or its agents but known to Teva, of the production equipment utilized in the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States.
  28. The extent of the actual and potential nitrosamine contamination of Teva's valsartan finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

**Quality Assurance and Quality Control Activities**

29. Teva's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in valsartan API evaluated by or purchased by Teva. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
30. Teva's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Teva's valsartan finished dose (regardless of intended sale location) in any facility that

manufactured Teva's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)

31. Teva's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.)

### **Process Development**

32. The modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modification, and (3) the relationship between the modifications and the nitrosamine contamination of ZHP's valsartan API.
33. Any evaluation conducted by or on behalf of Teva with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
34. Teva's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for ZHP's valsartan API.
35. Teva's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for Mylan's valsartan API.
36. Teva's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API.
37. Teva's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Mylan's valsartan API.
38. Teva's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Teva's valsartan finished dose.

### **Communications with Regulatory Agencies**

39. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
40. The communications with any regulatory authority, including but not limited to the FDA, with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Mylan's finished valsartan API.
41. Teva's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.
42. Teva's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of Mylan's valsartan API with nitrosamines including NDMA and NDEA.



43. Teva's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of Teva's valsartan finished dose with nitrosamines including NDMA and NDEA.

**Teva's Communications with API Manufacturers and Downstream Customers**

44. Teva's oral and written communications with ZHP with regard to the content/purity/contamination of ZHP's valsartan API.
45. Teva's oral and written communications with Mylan with regard to the content/purity/contamination of Mylan's valsartan API.
46. Teva's oral and written communications with its valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, related to the Teva finished dose.
47. Teva's oral and written statements (defined to include representations and warranties) to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Teva's finished dose.
48. Teva's product recall for valsartan finished dose, including who Teva communicated with, how, about what, and the retention of recalled or sequestered valsartan finished dose.
49. All credits, indemnification, refunds, and/or penalties paid or provided by or to Teva in connection with the nitrosamine contamination of valsartan.

**Compliance with cGMPs**

50. Teva's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of Teva's finished dose (regardless of intended sale location) in any facility that manufactured Teva's finished dose for sale in the United States. . (The parties to meet and confer to identify the relevant cGMP's.)

**Product Tracing**

51. Tracing of batches and lots of Teva's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.
52. The pricing of Teva's valsartan finished dose that was ultimately sold in the United States.
53. The gross and net profits to Teva from the sale of Teva's valsartan finished dose in the United States.
54. The quantity/units of Teva's valsartan finished dose sold in the United States.
55. The Teva valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).

**Corporate Relationships**

56. Teva's acquisitions and ownership of entities that purchased valsartan API and sold valsartan finished dose intended for use in the United States.

## Exhibit E

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

This Document Relates To:

*All Actions*

Hon. Robert. B. Kugler

Civ. No. 19-2875 (RBK/JS)

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO TORRENT PHARMACEUTICALS LIMITED AND TORRENT PHARMA INC.  
PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Alexia Brancato, Esq.  
Kirkland & Ellis LLP  
601 Lexington Avenue  
New York, NY 10022

*Counsel for Defendants Torrent Pharmaceuticals Limited and Torrent Pharma Inc.*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater

103 Eisenhower Parkway, Suite 207

Roseland, New Jersey 07068

Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on December 2, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Torrent Pharmaceuticals Limited and Torrent Pharma Inc., and Defendants' liaison counsel, via email.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**EXHIBIT A**

All topics reference information and documents known to, and/or in the possession, custody, or control, of Torrent, in the ordinary course of its business.

All references to Torrent include Torrent Pharmaceuticals Limited and Torrent Pharma Inc.

All references to the finished dose or Torrent's finished dose are defined to include the valsartan finished dose manufactured, sold, or distributed by Torrent, which was manufactured in the facilities that manufactured valsartan finished dose sold in the United States.

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of Torrent finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)

- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

**Testing of Valsartan API and Finished Dose**

1. The cause of the contamination of ZHP's valsartan API with nitrosamines including NDMA.
2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the ZHP API.
3. The testing performed by Torrent or its agents, to evaluate the purity and contents of ZHP's API.
4. The testing performed by Torrent or its agents, to evaluate the purity and contents of Torrent's finished dose.
5. The testing performed by any entity or person other than Torrent or its agents but known to Torrent, to evaluate the purity and contents of ZHP's valsartan API.
6. The testing performed by any entity or person other than Torrent or its agents but known to Torrent, to evaluate the purity and contents of Torrent's finished dose.
7. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of ZHP's valsartan API.
8. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of Torrent's finished dose.
9. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of ZHP's valsartan API.
10. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of Torrent's finished dose.
11. Torrent's evaluation of the potential risks to the purity or contents of ZHP's API posed or caused by solvents used during the API manufacturing process.
12. Torrent's evaluation of the potential risks to the purity or contents of Torrent's finished dose posed or caused by solvents used during the finished dose manufacturing process.
13. The chromatogram and mass spectrometry or other results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's valsartan API.
14. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of the solvents utilized in the manufacture of Torrent's finished dose.
15. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than ZHP or its agents but known to Torrent, of the solvents utilized in the manufacture of ZHP's API.
16. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of the solvents utilized in the manufacture of Torrent's finished dose.



17. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of the production equipment utilized in the manufacture of Torrent's finished dose.
18. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of the production equipment utilized in the manufacture of Torrent's finished dose.
19. The extent of the actual and potential nitrosamine contamination of Torrent's valsartan finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

#### **Quality Assurance and Quality Control Activities**

20. Torrent's SOP's/policies/procedures intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of valsartan API.
21. Torrent's SOP's/policies/procedures intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Torrent's finished dose.
22. Torrent's application of cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Torrent's finished dose.
23. Deleted.

#### **Process Development**

24. Deleted.
25. The modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modification, and (3) the relationship between the modifications and the nitrosamine contamination of ZHP's valsartan API.
26. Any evaluation conducted by or on behalf of Torrent with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, and in particular potential nitrosamine impurities, in the manufacturing process for ZHP's valsartan API.
27. Torrent's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for ZHP's valsartan API.
28. Torrent's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API.
29. Deleted.

**Communications with Regulatory Agencies**

30. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
31. Torrent's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.
32. Torrent's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of Torrent's valsartan finished dose with nitrosamines including NDMA and NDEA.

**Torrent's Communications with API Manufacturers and Downstream Customers**

33. Torrent's oral and written communications with ZHP with regard to the content/purity/contamination of ZHP's valsartan API.
34. Torrent's oral and written communications with its valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Torrent finished dose.
35. Torrent's oral and written statements (defined to include representations and warranties) to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Torrent's finished dose.
36. Torrent's product recall for valsartan finished dose, including who Torrent communicated with, how, about what, and the retention of recalled or sequestered valsartan finished dose.
37. All credits, indemnification, refunds, and/or penalties paid or provided by or to Torrent in connection with the nitrosamine contamination of valsartan (for example: Torrent-MDL2875-00100153).

**Compliance with cGMPs**

38. Torrent's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of Torrent's finished dose.
39. Deleted.

**Product Tracing**

40. Tracing of batches and lots of Torrent's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.
41. The pricing of Torrent's valsartan finished dose that was ultimately sold in the United States (the parties to meet and confer to identify relevant documents).

42. The gross and net profits to Torrent from the sale of Torrent's valsartan finished dose in the United States (the parties to meet and confer to identify relevant documents).
43. The quantity/units of Torrent's valsartan finished dose sold in the United States (the parties to meet and confer to identify relevant documents).
44. The Torrent valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).

**Corporate Relationships**

45. Torrent's acquisitions and ownership of entities that purchased valsartan API and sold valsartan finished dose intended for use in the United States.

## Exhibit F

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

This Document Relates To:

*All Actions*

Hon. Robert. B. Kugler

Civ. No. 19-2875 (RBK/JS)

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD,  
PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Seth Goldberg, Esq.  
Duane Morris LLP  
30 South 17th Street  
Philadelphia, PA 19103-4196

*Counsel for Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 2nd day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater

103 Eisenhower Parkway, Suite 207

Roseland, New Jersey 07068

Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on December 2, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai US Inc., Princeton Pharmaceutical Inc., and Solco Healthcare US, LLC, and Defendants' liaison counsel, via email.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**EXHIBIT A**

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues and the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

All topics reference information and documents known to, and/or in the possession, custody, or control of ZHP, in the ordinary course of its business.

All references to ZHP include Zhejiang Huahai Pharmaceutical Co., Ltd.

All references to Solco indicate Solco Healthcare US, LLC.

All references to Princeton indicate Princeton Pharmaceutical, Inc.

All references to Huahai indicate Huahai US, Inc.

All references to the API, ZHP's valsartan API, or ZHP's API are defined as valsartan API manufactured, sold, or distributed by ZHP, which was manufactured in the facilities that manufactured valsartan API sold in the United States.

All references to the finished dose, ZHP's valsartan finished dose, or ZHP's finished dose are defined as valsartan finished dose manufactured, sold, or distributed by ZHP, which was manufactured in the facilities that manufactured valsartan finished dose sold in the United States.

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

In accordance with the Court's Macro Discovery Order, all references to testing are defined as testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of ZHP's valsartan API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)



- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

**Testing of Valsartan API**

1. The cause of the contamination of ZHP's valsartan API with nitrosamines including NDMA.
2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the ZHP API.
3. The testing performed by ZHP or its agents, to evaluate the purity and contents of ZHP's API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
4. The testing performed by ZHP or its agents, to evaluate the purity and contents of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
5. The testing performed by any entity or person other than ZHP or its agents but known to ZHP, to evaluate the purity and contents of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
6. The testing performed by any entity or person other than ZHP or its agents but known to ZHP, to evaluate the purity and contents of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.

7. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
8. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
9. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
10. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
11. ZHP's evaluation of the potential risks to the purity or contents of ZHP's valsartan API posed or caused by solvents used during the manufacturing process (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
12. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
13. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
14. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the solvents utilized in the manufacture of ZHP's API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
15. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the solvents utilized in the manufacture of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
16. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the production equipment utilized in the manufacture of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
17. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the production equipment utilized in the manufacture of ZHP's valsartan finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.

18. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the production equipment utilized in the manufacture of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
19. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the production equipment utilized in the manufacture of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
20. The extent of the actual and potential nitrosamine contamination of ZHP's valsartan API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

**Quality Assurance and Quality Control Activities**

21. ZHP's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
22. ZHP's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of ZHP's valsartan finished dose (regardless of intended sale location) in any facility that manufactured ZHP's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
23. ZHP's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.)
24. ZHP's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of ZHP's finished dose (regardless of intended sale location) in any facility that manufactured ZHP's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.)

25. The “relevant SOP’s, QS, testing method, validation reports, equipment calibration records, preventive maintenance plan and change control records, etc.” referenced at b.6. on ZHP00004355.
26. The distinction between technical inquiries and deviation reports, as those terms are defined in ZHP’s documents and in the ordinary course of business.
27. The processes and procedures for handling technical inquiries.
28. The processes and procedures for handling deviation reports.
29. The technical inquiries received by ZHP relating to ZHP’s valsartan API, (regardless of intended sale location) in any facility that manufactured ZHP’s valsartan API for sale in the United States.
30. The technical inquiries received by ZHP relating to ZHP’s valsartan Finished Dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP’s finished dose for sale in the United States.
31. The deviation reports drafted by or received by ZHP relating to ZHP’s valsartan API (regardless of intended sale location) in any facility that manufactured ZHP’s valsartan API for sale in the United States.
32. The deviation reports drafted by or received by ZHP relating to ZHP’s valsartan Finished Dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP’s finished dose for sale in the United States.

### **Process Development**

33. The “primary process validation of Process II (Zn cl2) completed in April 2012” referenced on ZHP00004372.
34. The modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP’s valsartan API, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modification, and (3) the relationship between the modifications and the nitrosamine contamination of ZHP’s valsartan API (regardless of intended sale location) in any facility that manufactured ZHP’s valsartan API for sale in the United States.
35. Any evaluation conducted by or on behalf of ZHP with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP’s valsartan API (regardless of intended sale location) in any facility that manufactured ZHP’s valsartan API for sale in the United States. 35A. ZHP’s evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for ZHP’s valsartan API (regardless of intended sale location) in any facility that manufactured ZHP’s valsartan API for sale in the United States.
36. ZHP’s evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP’s valsartan API, and ZHP’s valsartan finished dose.
37. The process changes referenced in section 3.4.1 on ZHP00004371.

**Communications with Regulatory Agencies**

38. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
39. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's finished dose.
40. ZHP's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.
41. ZHP's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for ZHP's Valsartan API Drug Master Filings.

**ZHP's Communications with API and Finished Dose Customers and Downstream Customers**

42. ZHP's oral and written communications with Novartis with regard to the content/purity/contamination of ZHP's valsartan API.
43. ZHP's oral and written communications with ZHP's valsartan API Customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan API.
44. ZHP's oral and written communications with ZHP's valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan finished dose.
45. ZHP's oral and written statements (defined to include representations and warranties) to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of ZHP's valsartan API or ZHP's valsartan finished dose.
46. ZHP's product recall for ZHP's valsartan API or ZHP's valsartan finished dose, including who ZHP communicated with, how, about what, and the retention of recalled or sequestered ZHP valsartan API or ZHP valsartan finished dose.
47. All credits, indemnification, refunds, and/or penalties paid or provided by or to ZHP in connection with the nitrosamine contamination of ZHP's valsartan API and ZHP's valsartan finished dose.

**Compliance with cGMPs**

48. ZHP's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of ZHP's API and ZHP's valsartan finished dose (regardless of intended sale location) manufactured in

any facility that manufactured ZHP's valsartan API and ZHP's valsartan finished dose for sale in the United States.

49. The "GMP and process training" referenced in the Personnel section on ZHP00004368.

**Product Tracing**

- 50. Tracing of batches and lots of ZHP's valsartan API sold downstream and ultimately intended for use by consumers in the United States.
- 51. Tracing of batches and lots of ZHP's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.
- 52. The pricing of ZHP's valsartan API that was ultimately sold in the United States.
- 53. The pricing of ZHP's valsartan finished dose that was ultimately sold in the United States.
- 54. The gross and net profits to ZHP from the sale of ZHP's valsartan API in the United States.
- 55. The gross and net profits to ZHP from the sale of ZHP's valsartan finished dose in the United States.
- 56. The quantity/units of ZHP's valsartan API sold in the United States.
- 57. The quantity/units of ZHP's valsartan finished dose sold in the United States.
- 58. The ZHP valsartan API sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days in advance of deposition during the meet and confer process).
- 59. The ZHP valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days in advance of deposition during the meet and confer process).

## Exhibit G

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

This Document Relates To:

*All Actions*

Hon. Robert. B. Kugler

Civ. No. 19-2875 (RBK/JS)

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO HUAHAI US INC., PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Seth Goldberg, Esq.  
Duane Morris LLP  
30 South 17th Street  
Philadelphia, PA 19103-4196

*Counsel for Defendant Huahai US, Inc..*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 2<sup>nd</sup> day of December, 2020.



**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater

103 Eisenhower Parkway, Suite 207

Roseland, New Jersey 07068

Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on December 2, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Huahai US Inc., and Defendants' liaison counsel, via email.

DATED this 2nd day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**EXHIBIT A**

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues and the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

All topics reference information and documents known to, and/or in the possession, custody, or control of Huahai US Inc., in the ordinary course of its business.

All references to Huahai indicate Huahai US, Inc.

All references to ZHP indicate Zhejiang Huahai Pharmaceutical Co., Ltd.

All references to Princeton indicate Princeton Pharmaceutical, Inc.

All references to Solco indicate Solco Healthcare US, LLC.

All references to the API, ZHP's valsartan API, or ZHP's API are defined to include the valsartan API manufactured, sold, or distributed by ZHP, which was manufactured in any facility that manufactured ZHP's valsartan API sold in the United States.

All references to the finished dose, ZHP's valsartan finished dose, or ZHP's finished dose are defined to include valsartan finished dose manufactured, sold, or distributed by ZHP, which was manufactured in any facility that manufactured ZHP's valsartan finished dose sold in the United States.

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

In accordance with the Court's Macro Discovery Order, all references to testing are defined as testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of ZHP's valsartan API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)

- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

**Communications with Regulatory Agencies**

1. 38. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
2. 40. Disclosures by Huahai or by Huahai on behalf of ZHP, Solco, and/or Princeton to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and/or NDEA.
3. 41. Filings by Huahai or by Huahai on behalf of ZHP, Solco, and/or Princeton with regulatory authorities, including the FDA, regarding manufacturing process changes for ZHP's Valsartan API Drug Master Filings.

## Exhibit H

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

This Document Relates To:

*All Actions*

Hon. Robert. B. Kugler

Civ. No. 19-2875 (RBK/JS)

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO PRINSTON PHARMACEUTICAL INC., PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Seth Goldberg, Esq.  
Duane Morris LLP  
30 South 17th Street  
Philadelphia, PA 19103-4196

*Counsel for Defendant Prinston Pharmaceutical, Inc.*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater

103 Eisenhower Parkway, Suite 207

Roseland, New Jersey 07068

Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on December 2, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Princeton Pharmaceutical Inc., and Defendants' liaison counsel, via email.

DATED this 2nd day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***



**EXHIBIT A**

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues and the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

All topics reference information and documents known to, and/or in the possession, custody, or control of Princeton, in the ordinary course of its business.

All references to Princeton indicate Princeton Pharmaceutical, Inc.

All references to ZHP indicate Zhejiang Huahai Pharmaceutical Co., Ltd.

All references to Solco indicate Solco Healthcare US, LLC.

All references to Huahai indicate Huahai US, Inc.

All references to the API, ZHP's valsartan API, or ZHP's API are defined to include the valsartan API manufactured, sold, or distributed by ZHP, which was manufactured in the facilities that manufactured valsartan API sold in the United States..

All references to the finished dose, ZHP's valsartan finished dose, or ZHP's finished dose are defined to include the valsartan finished dose manufactured, sold, or distributed by ZHP, which was manufactured in the facilities that manufactured valsartan finished dose sold in the United States.

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and the presence of nitrosamines prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of ZHP's valsartan API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)

- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

### **Process Development**

1. 36. ZHP's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API, and ZHP's valsartan finished dose.

### **Communications with Regulatory Agencies**

2. 38. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
3. 39. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's finished dose.
4. 40. Disclosures by or on behalf of ZHP, Huahai US, Inc., Solco, and/or Princeton to regulatory authorities including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.

### **ZHP's Communications with API and Finished Dose Customers and Downstream Customers**

5. 44. Oral and written communications by or on behalf of ZHP, Huahai US, Inc., Solco, and/or Princeton with their valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan finished dose.
6. 46. ZHP's product recall for ZHP's valsartan API or ZHP's valsartan finished dose, including who ZHP, Huahai US, Inc., Solco, and/or Princeton communicated with, how, about what, and the retention of recalled or sequestered ZHP valsartan API or ZHP valsartan finished dose.

# Exhibit I

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

This Document Relates To:  
*All Actions*

Hon. Robert. B. Kugler

Civ. No. 19-2875 (RBK/JS)

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO SOLCO HEALTHCARE US, LLC PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Seth Goldberg, Esq.  
Duane Morris LLP  
30 South 17th Street  
Philadelphia, PA 19103-4196

*Counsel for Defendant Solco Healthcare US, LLC.*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 2nd day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN,  
LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on December 2, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Solco Healthcare US, LLC, and Defendants' liaison counsel, via email.

DATED this 2<sup>nd</sup> day of December, 2020.

**MAZIE SLATER KATZ & FREEMAN,  
LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**EXHIBIT A**

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues and the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

All topics reference information and documents known to, and/or in the possession, custody, or control of Solco, in the ordinary course of its business.

All references to Solco indicate Solco Healthcare US, LLC.

All references to ZHP indicate Zhejiang Huahai Pharmaceutical Co., Ltd.

All references to Prinston indicate Prinston Pharmaceutical, Inc.

All references to Huahai indicate Huahai US, Inc.

All references to the API, ZHP's valsartan API, or ZHP's API are defined to include the valsartan API manufactured, sold, or distributed by ZHP, which was manufactured in the facilities that manufactured valsartan API sold in the United States.

All references to the finished dose, ZHP's valsartan finished dose, or ZHP's finished dose are defined to include the valsartan finished dose manufactured, sold, or distributed by ZHP, which was manufactured in the facilities that manufactured valsartan finished dose sold in the United States.

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of ZHP's valsartan API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)



- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

#### **Testing of Valsartan API**

1. 20. The extent of the actual and potential nitrosamine contamination of ZHP's valsartan API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

#### **ZHP's Communications with API and Finished Dose Customers and Downstream Customers**

2. 44. Oral and written communications by or on behalf of ZHP, Huahai US, Inc., Solco, and/or Princeton with their valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan finished dose.
3. 45. Oral and written statements (defined to include representations and warranties) by or on behalf of ZHP, Huahai US, Inc., Solco, and/or Princeton to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of ZHP's valsartan API or ZHP's valsartan finished dose.
4. 46. ZHP's product recall for ZHP's valsartan API or ZHP's valsartan finished dose, including who ZHP, Huahai US, Inc., Solco, and/or Princeton communicated with, how, about what, and the retention of recalled or sequestered ZHP valsartan API or ZHP valsartan finished dose.
5. 47. All credits, indemnification, refunds, and/or penalties paid or provided by or to ZHP, Huahai US, Inc., Solco, and/or Princeton in connection with the nitrosamine contamination of ZHP's valsartan API and ZHP's valsartan finished dose.

**Product Tracing**

6. 51. Tracing of batches and lots of ZHP's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.
7. 53. The pricing of ZHP's valsartan finished dose that was ultimately sold in the United States.
8. 55. The gross and net profits to ZHP, Huahai US, Inc., Solco, and/or Princeton from the sale of ZHP's valsartan finished dose in the United States.
9. 57. The quantity/units of ZHP's valsartan finished dose sold in the United States.
10. 59. The ZHP valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).